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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BELYAVSKYI, MICHAIL A	

ART UNIT	PAPER NUMBER
1644	

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,247	MOSTOV ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 01/18/02 (Paper No: 3) is acknowledged.

Claims 1 –93 are pending.

Restriction Requirement

2. For examination purposes the following is noted : The construct recited in claims 11, 23, 39, 51,73 and 78 as "a ligand further defined as comprising a binding component and biologically active component" is viewed as a conjugate, fusion protein or complex consisting of a binding component (ligand) and a biological active component (a nucleic acid, a protein, a radioisotope, a lipid, a carbohydrate, a peptidometic, an anti-inflammatory, an antibiotic and anti-infective). These molecules differ with respect to their structure from a molecule recited in claim 1 as " a ligand that binds specifically to a region of a polymeric immunoglobulin receptor". Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-10, drawn to a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

II. Claims 1-14, drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is nucleic acid, classified in Class 530, subclass 350; class 424, subclass 193.1

III. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is a protein, classified in Class 530, subclass 350; class 424, subclass 193.1.

IV. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is a radioisotope, classified in Class 530, subclass 350; class 424, subclass 193.1.

V. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is a lipid, classified in Class 530, subclass 350; class 424, subclass 193.1.

VI. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is a carbohydrate, classified in Class 530, subclass 350; class 424, subclass 193.1.

VII. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is a peptidomimetic, classified in Class 530, subclass 350; class 424, subclass 193.1.

VIII. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is an anti-inflammatory, classified in Class 530, subclass 350; class 424, subclass 193.1.

IX. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is an antibiotic, classified in Class 530, subclass 350; class 424, subclass 193.1.

X. Claims 1-12, and 14 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is an anti-infective, classified in Class 530, subclass 350; class 424, subclass 193.1.

XI. Claims 1-12, and 15 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component is a small molecule, classified in Class 530, subclass 350; class 424, subclass 193.1.

XII. Claim 16 drawn to a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to a peptide comprising 31 amino acid that are cell-membrane proximal to the initial cleavege site, classified in Class 530, subclass 350; class 424, subclass 184.1.

XIII. Claims 17 –22 and 27-29 drawn to a method of introducing a ligand into a cell wherein said ligand binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

XIV. Claims 17-25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is nucleic acid, classified in Class 530, subclass 350; class 424, subclass 193.1

XV. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a protein, classified in Class 530, subclass 350; class 424, subclass 193.1.

XVI. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a radioisotope, classified in Class 530, subclass 350; class 424, subclass 193.1.

XVII. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a lipid, classified in Class 530, subclass 350; class 424, subclass 193.1.

XVIII. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a carbohydrate, classified in Class 530, subclass 350; class 424, subclass 193.1.

XIX. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a peptidomimetic, classified in Class 530, subclass 350; class 424, subclass 193.1.

XX. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an anti-inflammatory, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXI. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an antibiotic, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXII. Claims 17-23, 25 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an anti-infective, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXIII. Claims 17-23, 26 and 27-29 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a small molecule, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXIV. Claim 30 drawn to a method of introducing a ligand into a cell wherein said ligand binds specifically to a region of a polymeric immunoglobulin receptor and does not substantially bind to the stalk of pIgR and does not substantially bind to a peptide comprising 31 amino acid that are cell-membrane proximal to the initial cleavage site, classified in Class 530, subclass 350; class 424, subclass 184.1.

XXV. Claim 31 is drawn to a method of increasing the rate by which a first ligand which binds to secretory component is internalized into a cell secreting a polymeric immunoglobulin receptor, classified in Class 530, subclass 350; class 424, subclass 184.1.

XXVI. Claims 32-38 , drawn to a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

XXVII. Claims 32-40 and 42-43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is nucleic acid, classified in Class 530, subclass 350; class 424, subclass 193.1

XXVIII. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a protein, classified in Class 530, subclass 350; class 424, subclass 193.1

XXIX. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a radioisotope, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXX. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a lipid, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXI. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a carbohydrate, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXII. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a peptidomimetic, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXIII. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is an anti-inflammatory, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXIV. Claims 32 –40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is an antibiotic, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXV. Claims 32 -40 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is an anti-infective, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXVI. Claims 32 –39 , 41 and 43 drawn to a conjugate, fusion protein or complex , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a small molecule, classified in Class 530, subclass 350; class 424, subclass 193.1.

XXXVII. Claims 44 –50 and 56-63 drawn to a method of introducing a ligand into a cell wherein said ligand binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

XXXVIII. Claims 44-52, 54 and 55 -63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is nucleic acid, classified in Class 530, subclass 350; class 424, subclass 193.1

XXXIX. Claims 44-52, 54 and 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a protein, classified in Class 530, subclass 350; class 424, subclass 193.1.

XL Claims 44-52, 54 and 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a radioisotope, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLI Claims 44-52, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a lipid, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLII. Claims 44-52, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a carbohydrate, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLIII. Claims 44-52, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a peptidomimetic, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLIV. Claims 44-52, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is an anti-inflammatory, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLV. Claims 44-52, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is an antibiotic, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLVI. Claims 44-52, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is an anti-infective, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLVII. Claims 44-51, 53, 54, 56-63 drawn to a method of introducing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that binds specifically to a region of a polymeric immunoglobulin receptor , provided that binding of the ligand reduces proteolytic cleavage of secretory component and does not substantially bind to the stalk of pIgR and biological active component is a small molecule, classified in Class 530, subclass 350; class 424, subclass 193.1.

XLVIII. Claims 64-65 drawn to a method of attaching a ligand to a cell expressing a polymeric immunoglobulin receptor, classified in Class 530, subclass 350; class 424, subclass 184.1.

XLIX. Claim 66 drawn to a method of attaching a conjugate, fusion protein or complex to a cell expressing a polymeric immunoglobulin receptor, classified in Class 530, subclass 350; class 424, subclass 184.1.

L. Claims 67-72 and 76-78 drawn to a method of transcytosing a ligand from an apical to a basolateral side of the cell wherein said ligand does not substantially bind to the stalk of pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

LI. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is nucleic acid, classified in Class 530, subclass 350; class 424, subclass 193.1

LII. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a protein, classified in Class 530, subclass 350; class 424, subclass 193.1.

LIII. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a radioisotope, classified in Class 530, subclass 350; class 424, subclass 193.1.

LIV. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a lipid, classified in Class 530, subclass 350; class 424, subclass 193.1.

LV. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a carbohydrate, classified in Class 530, subclass 350; class 424, subclass 193.1.

LVI. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a peptidomimetic, classified in Class 530, subclass 350; class 424, subclass 193.1.

LVII. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an anti-inflammatory, classified in Class 530, subclass 350; class 424, subclass 193.1.

LVIII. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an antibiotic, classified in Class 530, subclass 350; class 424, subclass 193.1.

LIX. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an anti-infective, classified in Class 530, subclass 350; class 424, subclass 193.1.

LX. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is peptide, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXI. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an antisence oligonucleotide, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXII. Claims 67-73 and 75-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a small molecule, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXIII. Claims 79 drawn to a method of transcytosing a ligand from an apical to a basolateral side of the cell wherein said ligand does not substantially bind to the stalk of pIgR and does not bind to an extracellular epitope within the first 31 amino acids that are cell membrane proximal to the initial cleavage site of the pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

LXIV. Claims 80 –86 and 90-92 drawn to a method of transcytosing a ligand from an apical to a basolateral side of the cell provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR, classified in Class 530, subclass 350; class 424, subclass 184.1.

LXV. Claims 80-88, 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is nucleic acid, classified in Class 530, subclass 350; class 424, subclass 193.1

LXVI. Claims 80-88, 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a protein, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXVII. Claims 80-88, 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a radioisotope, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXVIII. Claims 80-88, 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a lipid, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXIX. Claims 80-88 and 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a carbohydrate, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXX. Claims 80-88 and 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a peptidomimetic, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXI. Claims 80-88 and 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an anti-inflammatory, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXII. Claims 80-88 and 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an antibiotic, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXIII. Claims 80-88, 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an anti-infective, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXIV. Claims 80-88, 90-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is peptide, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXV. Claims 67-74 and 76-78 drawn to a method of transcytosing a conjugate, fusion protein or complex into a cell , wherein binding component is a ligand that does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is an antisence oligonucleotide, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXVI. Claims 80-87, 89-92 drawn to a method of transcytosing a conjugate, fusion protein or complex from an apical to a basolateral side of the cell, wherein binding component is a ligand provided that binding of the ligand reduces proteolytic cleavage of secretory component and wherein said ligand does not substantially bind to the stalk of pIgR and biological active component of said conjugate, fusion protein or complex is a small molecule, classified in Class 530, subclass 350; class 424, subclass 193.1.

LXXVII. Claim 93 drawn to a method of increasing the rate by which a first ligand which binds to secretory component is transcytosed from an apical to a basolateral side of a cell, classified in Class 530, subclass 350; class 424, subclass 184.1

4. Groups I-XII, XXVI –XXXVI are different products. Ligand, a conjugate, fusion protein or complex consisting of a binding component (ligand) and a biological active component (a nucleic acid, a protein, a radioisotope, a lipid, a carbohydrate, a peptidometic, an anti-inflammatory, an antibiotic, and anti-infective) differ with respect to their structures physicochemical properties and mode of action; therefore each product is patentably distinct.

5. Groups XIII –XXV, XXXVIII-LXXII are different methods. These invention are different with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups I-XII / XIII-XXIV and XXVI –XXXVI/ XXXVII-XLXII and are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the ligands and conjugate, fusion protein or complex Groups I –XII and XXVI-XXXVI can be used for crystallography in addition to recited methods.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

8. If any of Groups I –LXXVIII is elected applicant is required to elect a specific **patentable distinct sequences** from the group recited in claims 8, 9, 21, 22,37,38,49,50,71,72, 85 and 86.

Each sequence is patentably distinct because they are unrelated sequences and further restriction is applied to each group. For each elected group using **patentable distinct sequences** from the group recited in claims 8, 9, 21, 22,37,38,49,50,71,72, 85 and 86 Applicant must further elect a single sequence. (See MPEP 803.04).
In view of limited office resources , only a single nucleic or amino acid sequence will be examined in this application. In addition, to the specific selected sequence, those sequences which are patentably indistinct from the selected sequences will be also examined.
Examination will be restricted to only the elected sequences.

9. If Group I is elected, Applicant is required to elect a specific organ of interest selected from the group recited in Claims 10.
These species are distinct because their structure, physicochemical properties and mode of action are different. The examination of species would require different searches in the scientific literature.

10. If any of Groups XIII –XXIII, XXXVII-XLVII, L-LXII is elected, applicant is required to elect a specific method of introducing a ligand into a cell or specific method of transcytosing a conjugate, fusion protein or complex into a cell , wherein a specific organ of interest selected from the group recited in Claims 29, 63,78.

These species are distinct because a specific method of introducing a ligand into a cell or specific method of transcytosing a conjugate, fusion protein or complex into a cell , wherein a specific organ of interest selected from the group recited in Claims 29, 63,78 differ with respect to the specific test aorgan of interest and the endpoint of the method; thus each specific method employing a specific organ of interest represents patentably distinct subject matter.

11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Technology Center 1600
March 21, 2003

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